IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0943/017/001
Case No: 2070789

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Transferred from PA0979/017/001.

Alliance Pharmaceuticals Ltd.

Avonbridge House, **Bath Road, Chippenham**, **Wiltshire SN15 2BB**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Timodine Cream

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **18/12/2009**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Timodine Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

	% w/w
Nystatin	3.00
Dimeticone 350	10.00
Hydrocortisone	0.50
Benzalkonium chloride solution (50% w/v) (equivalent to benzalkonium chloride 0.10g in 100g of cream)	0.20
Also Contains	
Cetostearyl Alcohol	1.51%
Butylated hydroxyanisol compound (E320)	0.4%
Methyl hydroxybenzoate (E218)	0.1%
Propyl Hydroxybenzoate (E216)	0.1%
Sorbic Acid	0.1%

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
A pale yellow cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the topical treatment of corticosteroid sensitive dermatoses and pruritus ani et vulvae, in which infection with *Candida albicans* may be a factor.

4.2 Posology and method of administration

For topical application to the skin.

Adults (including the elderly)

Apply three times daily or as directed by the physician and as indicated by the area involved.

Children

As directed by the physician.

4.3 Contraindications

Use in the presence of infections of viral, treponemal or tuberculous origin, or of untreated infections due to bacteria or fungi.

Use in acne vulgaris or rosacea, or in peri oral dermatoses.

Use in patients hypersensitive to the active ingredients.

4.4 Special warnings and precautions for use

Do not use on children under 12 years of age without medical supervision. This product should be applied sparingly for the shortest duration possible.

Continuous treatment for longer than three weeks should be avoided in patients under the age of three years because of the possibility of adreno-cortical suppression.

Prolonged use of uninterrupted occlusion or use with extensive occlusive dressings may suppress adrenocortical function.

Continuous application without interruption will result in local atrophy of the skin, striae and superficial vascular dilatation, particularly on the face.

Keep away from the eyes.

For external use only.

Keep out of reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. The relevance of this finding to human beings has not been established, however, topical steroids should not be used in pregnancy unless considered essential by the physician and should not then be used in large amounts or for prolonged periods.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

None known.

4.9 Overdose

No special procedures are likely to be needed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Nystatin

Nystatin is used for the prophylaxis and treatment of candidiasis of the skin and mucous membranes. It is an antifungal antibiotic, which is both fungistatic and fungicidal against a wide range of yeasts and yeast-like fungi.

Dimeticone

Dimeticone and other silicones are water-repellent and have a low surface tension. They are used in topical barrier preparations for protecting the skin against water-soluble irritants.

Hydrocortisone

Hydrocortisone is a mild, but effective anti-inflammatory agent.

Benzalkonium chloride

Benzalkonium chloride is a quaternary ammonium antiseptic with a broad spectrum of antibacterial activity.

5.2 Pharmacokinetic properties

Nystatin

Nystatin is not absorbed through the skin.

Dimeticone

Dimeticone is a silicone polymer that is not absorbed.

Hydrocortisone

Hydrocortisone is absorbed through the skin, metabolised in the liver and excreted in the urine. It has a short biological half-life of about 100 minutes and its metabolites are also excreted in the urine.

Benzalkonium chloride

Quaternary ammonium salts, such as benzalkonium chloride, are poorly absorbed through the skin.

5.3 Preclinical safety data

No preclinical findings of relevance to the prescriber have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dibutyl phthalate
Glyceryl monostearate (self emulsifying)
Stearic acid
Cetostearyl alcohol
Cellulose nitrate
Butylated hydroxyanisole compound (E320)
Sodium metabisulphite (E223)

Methyl hydroxybenzoate (E218)
Propyl hydroxybenzoate (E216)
Sorbic acid
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Two years.

6.4 Special precautions for storage

Store in a refrigerator at $2^{o}C$ – $8^{o}C$ in the original container with the cap tightly closed.
Do not freeze.

6.5 Nature and contents of container

Collapsible aluminium tubes with diaphragm and an internal lacquer coating of araldite resin.

Pack sizes: 5.5 g, 7.5g and 30 g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Alliance Pharamceuticals Limited
Avonbridge House
Bath Road
Chippenham SN15 2BB
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 0943/017/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 April 1978

Date of last renewal: 10 April 2008

10 DATE OF REVISION OF THE TEXT

December 2009